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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,126	01/12/2001	Kazuhiro Tsujita	Q61243	8903

<sup>7590</sup>  
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC  
2100 Pennsylvania Avenue, N.W.,  
Washington, DC 20037-3202

EXAMINER
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ROZANSKI, MICHAEL T

ART UNIT	PAPER NUMBER
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3768

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/26/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	Application No. 09/758,126	Applicant(s) TSUJITA ET AL.	
	Examiner Michael Rozanski	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 33-47 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 and 33-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-15 and 33-47 have been considered but are moot in view of the new ground(s) of rejection.

### ***Claim Objections***

2. Claims 39-43 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claims merely recite the response of the tissue to excitation light, which is a natural process rather than how the invention utilizes that response to provide a useful result. As such these responses do not further limit.

### ***Claim Rejections - 35 USC § 101***

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 39-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite the natural response of a tissue to excitation light. As such they do not fall under the statutory categories of invention.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-15 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. '190 (US 5,827,190) in view of Richards-Kortum et al (US 5,421,337).

Palcic et al. teach normalization of at least one fluorescence image by using a remittance image or as otherwise stated, reflected reference light image, in order to correct for many factors including light intensity allowing for differentiation of normal and diseased tissue (col. 2, line 20-col. 3, line 37). Palcic et al. teaches the use of a remittance image to account for non-uniformity due to different changes including illumination intensity (col. 2, lines 28-31).

While Palcic et al. do not specifically address specified values, it would have been obvious to one skilled in the art at the time that the invention was made that the normalization process necessarily incorporates specified values or

With respect to claims 33-43, necessarily the detected values of fluorescence will be above or below the remittance value depending on whether the tissue is normal or abnormal.

In addition, Palcic et al. do not teach that diseased tissue will have a higher intensity, and that normal tissue will have a lower intensity (as described in col. 6, lines 44-51). In the same field of endeavor, Richards-Kortum et al. teach of adenomatous tissue with higher intensity and normal tissue with lower intensity, both with reference to a specified wavelength value (col. 11, lines 3-10; col. 12, line 64-col. 13, line 15). It would have been obvious to one with ordinary skill in the art at the time the invention was made to improve the diagnosis of tissues regarding the condition of tissue.

With respect to claim 33 and newly added claims 44-47, Palcic et al. also do not specifically mention chrominance or luminance signal components with respect to the fluorescence image and reflected reference light or judgment means based on a ratio. However, Richards-Kortum et al. make reference to correlation features of fluorescence spectra to tissue type in a quantitative way using ratios of fluorescence intensities at various wavelengths from the fluorescent image and reflected reference light (col. 9, lines 10-34). In addition, color (chrominance) and intensity (luminance) components of autofluorescence are recorded for analysis (col. 21, lines 15-55). It would have been obvious to one with ordinary skill in the art at the time the invention was made to improve the diagnosis of tissues by through a better display of fluorescence images.

### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

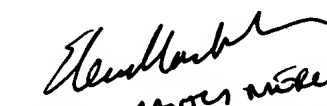
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



MR



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SPE ART UNIT 3768